K052661

JUN - 7 2006

Section 10 Administrative Requirements

510(k) Summary of Safety and Effectiveness

1. Submitter :

EDGE MEDICAL DEVICES Ltd.
25 Hatasia St.
P.O. Box 2126
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Israel

Contact:
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972-9-7413675
September, 2005

2. Device Name:

Classification Name:	Solid State X-ray Imaging Device
Common/Usual Name	Flat Panel Digital Imager
Proprietary Name	Quix Digital Radiography Upgrade

3. Equivalent Devices:

Proprietary Name:	**AGFA CP-B 200 screen / AGFA CP-BU New film**	**Fuji CR 5501D**	**Infimed Stingray DR System**
510(k) Numbers:	**exempt from 510(k)**	**K993861**	**K992794**
Common Name:	Analog Screen-Film system	Computed Radiography System	Digital Radiography System
Regulatory Class:	Class I (screen and film)	Class II	Class II
Classification Panel:	Radiology	Radiology	Radiology
Product Code:	892.1960 (screen) 892.1840 (film)	90IXW 892.1900	90MQB 892.1650

4. Device Description:

The Quix Digital Radiography Upgrade enables a conventional film-screen X-ray system to perform digital radiography exams by replacing the film-screen and the film-screen bucky with a digital bucky and operator console. The digital bucky incorporates a selenium-based flat panel detector with 16" x 17" imaging area. Images are displayed in approximately 10 seconds after exposure over a wide range

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of dose settings. The operator console provides local image storage and communicates with other network devices using DICOM 3.0 protocols.

5. Statement of Intended Use:

The Quix Digital Radiography Upgrade is based on a solid state imaging device and is intended for use in general radiographic examinations and applications wherever conventional film-screen systems may be used, excluding mammography, fluoroscopy, and angiography.

6. Comparison to substantially equivalent devices:

AGFA CP-B 200 screen / AGFA CP-BU New film
Fuji Computed Radiography System K993861
Infimed Stingray Digital Radiography System K992774

The following chart depicts the comparison characteristics.

Item	Current Device	Predicate Device	Predicate Device	Predicate Device
Device	Quix DR Upgrade	AGFA CP-B 200 screen / AGFA CP-BU New film	Fuji CR System	Infimed Stingray DR Upgrade
510(k) Number		exempt from 510(k)	K993861	K992794
Intended Use	Provide diagnostic images for general radiographic use	Same	Same	Same
Anatomical Sites	General radiography	Same	Same	Same
Target Population	General population	Same	Same	Same
Design	Digital acquisition, electronic processing	Analog acquisition, chemical processing	Digital acquisition, electronic processing	Digital acquisition, electronic processing
X-ray Converter	Amorphous selenium, converts X-rays to latent charge image	Fluorescent screen, converts X-rays to light	Photostimulable phosphor imaging plate converts X-rays to stable exited states of the material	Cesium Iodide scintillator, converts X-rays to light
Image Readout	Plasma DR Readout Technology – line scanner sweeps across sensor surface to readout latent charge image.	Silver halide film	Mechanical scanner sweeps Laser across phosphor surface to readout latent stored image.	Photodiode and TFT amorphous silicon active matrix array convert light to electrical charge which is readout electronically.
Moving line scanner	Yes	No	Yes	No
Performance	Digital image processing (optimized gray scale)	Chemical processing (fixed gray scale)	Digital image processing (optimized gray scale)	Digital image processing (optimized gray scale)
Imaging area	16" x 17"	14" x 17"	14" x 17"	17" x 17"
Monolithic sensor	Yes	Yes	Yes	No (tiled subarrays)
Pixel array size	2540 x 2700	N/A	2140 x 2140	2981 x 3021 (from 510(k)) 3000 x 3000 (current "chart smart")

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Item	Current Device	Predicate Device	Predicate Device	Predicate Device
Device	Quix DR Upgrade	AGFA CP-B 200 screen / AGFA CP-BU New film	Fuji CR System	Infimed Singray DR Upgrade
Pixel size	160 µm	<100 µm	200 µm in standard mode 100 µm in high density mode	143 µm
Dynamic Range	12 bits (4,096)	Approximately x50	10 bits (1,024)	14 bits (16,384)
Connectivity	DICOM 3.0 Compatible	N/A	DICOM 3.0 Compatible	DICOM 3.0 Compatible
Image processing time	10 sec	90 sec	3-5 minutes per image	30 sec (from 510(k)) <8 sec (current "chart smart")
Spatial resolution	0.7 @ 1lp/mm 0.35@ 2lp/mm 0.1 @ 3lp/mm	N/A	Standard mode: 0.65 @ 1lp/mm 0.3@ 2lp/mm 0.1@ 3lp/mm High density mode: 0.8 @ 1lp/mm 0.5@ 2lp/mm 0.3@ 3lp/mm	0.7 @ 1lp/mm 0.35@ 2lp/mm 0.15 @ 3lp/mm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN - 7 2006

Vered Scharf, Ph.D.
R&D Manager
EDGE Medical Devices Ltd.
25 Hatasiya
P.O. Box 2126
Raanana Ind. Zone, 43654
ISRAEL

Re: K052661
Trade/Device Name: Quix Digital Radiography Upgrade
Regulation Number: 21 CFR §892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: April 20, 2006
Received: May 2, 2006

Dear Dr. Scharf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known): K052661

Device Name: Quix Digital Radiography Upgrade

Indications for Use:

The Quix Digital Radiography Upgrade is based on a solid state imaging device and is intended for use in general radiographic examinations and applications wherever conventional film-screen systems may be used, excluding mammography, fluoroscopy, and angiography.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052661

Prescription Use √